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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/770,943	01/25/2001	Eyal Raz	UCAL173CON	8209

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BOZICEVIC, FIELD & FRANCIS LLP
1900 UNIVERSITY AVENUE
SUITE 200
EAST PALO ALTO, CA 94303

EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/770,943	RAZ ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-36 and 38-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36 and 38-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment filed 1-24-06 has been entered into the record. Claims 32-36 and 38-43 are pending and examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

The allowability of claim 37 is withdrawn in view of newly discovered references providing motivation to conjugate a peptide to the ODN.

New Rejections

Claim 40 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Draper et al (US Patent No. 5,514,577 issued May 7, 1996) for reasons made of record in the Office Action mailed 11-14-05.

Draper et al teach a wide variety of pharmaceutical compositions comprising oligonucleotides, nucleic acid analogs and carriers/buffers/diluents, excipients (see column 7 line 25-column 8, line 7 and column 9, lines 1-43). In particular Draper et al teach SEQ ID NO:47, 48 and 51. SEQ ID NO:47 having the sequence of GTTGGAGACC***GGIGTT***GIG, SEQ ID NO:48 having the sequence GTTGGAGACC***GGGITT***GGGG, and SEQ ID NO:51 having the sequence GTTGGAGACC***GGGGTT***GGGI (see Table 4, columns 13-14). Each of the sequences set forth in SEQ ID NOS:47, 48 and 51 are less than 45 nucleotides in length. As such, Draper et al the pharmaceutical compositions comprising the recited sequences anticipate the instantly claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al (WO 91/16901, published November 14, 1991) in view of Barsoum et al (WO 94/04686, published March 3, 1994).

The claims are drawn to a nucleic acid comprising a hexameric sequence of a particular structure in a pharmaceutically acceptable carrier, wherein the nucleic acid is 6 to 45 nucleotides in length or the hexameric structure is AAGGTT (see claim 36) wherein the nucleic acid is conjugated to a peptide.

Bennett et al teach a nucleic acid of SEQ ID NO:12 (GG***AAGGTT***TCCAGGGAAGAGG) wherein the nucleic acid or nucleic acid analog is in a

pharmaceutically acceptable carrier (see pages 53-54, claims 18 and 19). Bennett et al teach analogs encompass phosphorothioate moieties or linking groups between nucleotide units are sulfur containing species (see page 54, claims 20 and 21). As such, Bennett et al anticipate the instantly claimed invention. Bennett et al differs by not conjugating to a peptide.

Barsoum et al teach the delivery of cargo molecules, such as nucleic acids to the cytoplasm and nuclei of cells in vitro and in vivo by the use of a transport polypeptides that comprise one or more portions of HIV tat protein which are covalently attached to cargo molecules (see abstract and pages 5-7)

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to conjugate nucleic acid of Bennett et al to the transport peptide(s) of Barsoum et al because Barsoum et al teach that the cargo peptides facilitate and enhance entry of nucleic acids into the cytoplasm and nucleic of cells *in vitro* and *in vivo*.

Claim 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable aver Draper et al (US Patent No. 5,514,577 issued May 7, 1996) in view of Barsoum et al (WO 94/04686, published March 3, 1994).

Draper et al teach a wide variety of pharmaceutical compositions comprising oligonucleotides, nucleic acid analogs and carriers/buffers/diluents, excipients (see column 7 line 25-column 8, line 7 and column 9, lines 1-43). In particular Draper et al teach SEQ ID NO:47, 48 and 51. SEQ ID NO:47 having the sequence of GTTGGAGACC***GGIGTT***GIG, SEQ ID NO:48 having the sequence GTTGGAGACC***GGGITT***GGGG, and SEQ ID NO:51 having the sequence GTTGGAGACC***GGGGTT***GGGI (see Table 4, columns 13-14). Each of the sequences set forth in SEQ ID NOS:47, 48 and 51 are less than 45 nucleotides in length. Draper differs by not conjugating to a peptide.

Barsoum et al teach the delivery of cargo molecules, such as nucleic acids to the cytoplasm and nuclei of cells in vitro and in vivo by the use of a transport polypeptides that comprise one or more portions of HIV tat protein which are covalently attached to cargo molecules (see abstract and pages 5-7)

It would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to conjugate nucleic acids of Draper et al to the transport peptide(s) of Barsoum et al because Barsoum et al teach that the cargo peptides facilitate and enhance entry of nucleic acids into the cytoplasm and nucleic of cells *in vitro* and *in vivo*.

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Draper et al (US Patent No. 5,514,577 issued May 7, 1996) and Barsoum et al (WO 94/04686, published March 3, 1994) as applied to claims 40 and 41 above, and further in view of Bennett et al (WO 91/16901, published November 14, 1991).

The combination of Draper et al and Barsoum et al is set forth supra. The combination differs by not having phosphorothioate linkages in the nucleic acid.

Bennett et al teach that oligonucleotide analogs such as phosphorothioate function to enhance the ability of the compositions to penetrate into regions of the cells where the RNA and DNA whose activity is to be modulated (page 27) and such analogs are well known to have the advantage of being resistant to degradation by endogenous or exogenous nucleases.

It would have been prima facie obvious to one having ordinary skill in the art to modify the nucleic acid in the composition as combined supra to substitute native linkages with analog linkages as taught by Bennett et al because Bennett et al teach that oligonucleotide analogs such as phosphorothioate function to enhance the ability of the compositions to penetrate into regions of the cells where the RNA and DNA whose activity

is to be modulated and that such linkages are well known to be resistant to exogenous and endogenous nuclease.

Status of Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy
Primary Examiner
Art Unit 1645